

Exhibit C

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 9, 2016

OCULAR THERAPEUTIX, INC.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36554
(Commission
File Number)

20-5560161
(IRS Employer
Identification No.)

**34 Crosby Drive, Suite 105
Bedford, MA 01730**
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: (781) 357-4000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On August 9, 2016, Ocular Therapeutix, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 2016. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release of Ocular Therapeutix, Inc., dated August 9, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OCULAR THERAPEUTIX, INC.

Date: August 9, 2016

By: /s/ W. Bradford Smith

W. Bradford Smith
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Ocular Therapeutix, Inc., dated August 9, 2016.

EX-99.1 2 d208051dex991.htm EX-99.1

Exhibit 99.1

Ocular Therapeutix™ Reports Second Quarter 2016 Financial Results and Provides Corporate Update*Conference call today at 8:30 am Eastern Time*

BEDFORD, Mass, August 9, 2016 (BUSINESS WIRE): Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the second quarter ended June 30, 2016.

“The second half of 2016 will be a busy time for Ocular Therapeutix as we prepare to initiate the first of two planned Phase 3 clinical trials with OTX-TP for the treatment of glaucoma and ocular hypertension during the third quarter,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “Regarding our NDA for DEXTENZA for the treatment of post-surgical ocular pain, labeling discussions with the FDA are ongoing, and as we just announced, we are working to resolve the one remaining open manufacturing observation identified by the FDA in connection with their facility inspection. We will continue to work collaboratively with the FDA so they can finalize their review of our NDA, and we remain committed to bringing DEXTENZA to market.”

Recent Highlights and Anticipated Near-Term Milestones for Key Development Programs***DEXTENZA for the treatment of post-surgical ocular inflammation and pain***

- A New Drug Application (NDA) for DEXTENZA (dexamethasone insert) 0.4 mg, for intracanalicular use in the treatment of ocular pain occurring after ophthalmic surgery is pending with the U.S. Food and Drug Administration (FDA).
 - In July 2016, Ocular Therapeutix received a complete response letter (CRL) from the FDA that identified issues pertaining to deficiencies in the manufacturing process and controls, originally identified during a pre-NDA approval inspection of the Company’s manufacturing facility. The CRL for DEXTENZA did not identify efficacy or safety concerns with respect to the clinical data provided in the NDA nor any need for additional clinical trials for the approval of the NDA.
 - The FDA recently issued a letter noting that the corrective actions detailed in the Company’s responses as a whole appear to address the ten inspectional observations raised in the Form 483 with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the DEXTENZA manufacturing process. The FDA also requested that the Company provide evidence (e.g., a final report) when migration to automatic integration of analytical testing is complete, which is anticipated during the third quarter of 2016.

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- Should the FDA grant marketing approval for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery by the end of 2016, the Company expects to apply for a pass-through reimbursement code used in the hospital and ambulatory surgery center setting and launch this product in the first half of 2017.
- Ocular Therapeutix has completed enrollment in a third Phase 3 clinical trial for DEXTENZA for post-surgical ocular inflammation and pain.
 - The Company expects topline results from the trial to be available in the fourth quarter of 2016.
 - If the Company obtains favorable results from this third Phase 3 trial and subject to approval of the NDA for post-surgical ocular pain by the FDA, the Company intends to submit an NDA supplement for DEXTENZA aiming to broaden the label to include a post-surgical inflammation indication.

DEXTENZA for the treatment of allergic conjunctivitis

- To date, the Company has conducted two Phase 3 clinical trials for DEXTENZA for the treatment of allergic conjunctivitis. The first trial met the primary endpoint for ocular itching. In June 2016, the Company reported that the second trial did not meet the single primary efficacy endpoint of ocular itching.
- Following the second Phase 3 trial, a meeting was held with the FDA to discuss the results. Pending receipt of written feedback from the FDA, the Company will provide further guidance on the clinical development path forward for this indication at a later time.

DEXTENZA for the treatment of dry eye disease

- Ocular Therapeutix has completed a Phase 2 clinical trial of DEXTENZA for the treatment of dry eye. In this trial, signs of total corneal staining decreased by a statistically significant level from baseline in the DEXTENZA group compared to placebo group.
- A range of objective and subjective measures (signs and symptoms, respectively) and potential clinical trial designs are being evaluated for additional clinical development in dry eye-related indications.

OTX-TP (sustained release travoprost) for the treatment of glaucoma and ocular hypertension

- Ocular Therapeutix plans to initiate the first of two planned Phase 3 clinical trials for OTX-TP (sustained release travoprost) for the treatment of glaucoma and ocular hypertension during the third quarter of 2016.
 - The primary efficacy endpoint will be the reduction of intraocular pressure (IOP) from baseline in the OTX-TP treatment arm compared to a placebo arm.

- Importantly, the Phase 3 study design will not include a timolol comparator or validation arm, and will not have active or placebo eye drops administered in either arm.

Second Quarter 2016 Financial Results

- As of June 30, 2016, cash, cash equivalents and marketable securities totaled \$83.9 million. Cash used in operating activities was \$9.8 million in the second quarter of 2016, compared to \$8.5 million for the second quarter of 2015. There was \$15.6 million in outstanding debt as of June 30, 2016 and no principal payments are due until January 2017. The Company expects that cash, cash equivalents and marketable securities will be sufficient to fund operating expenses, debt service obligations and capital expenditures through the third quarter of 2017.
- Ocular Therapeutix reported a net loss of approximately \$11.4 million, or \$(0.46) per share, for the quarter ended June 30, 2016, compared to a net loss of \$10.0 million, or \$(0.45) per share, for the quarter ended June 30, 2015. The second quarter 2016 results include \$1.5 million in non-cash charges for stock-based compensation compared to \$1.2 million in such non-cash charges in the second quarter of 2015.
- Total costs and operating expenses for the quarter ended June 30, 2016 were \$11.5 million, as compared to \$10.1 million for the quarter ended June 30, 2015. Research and development (R&D) expenses for the quarter ended June 30, 2016 were \$7.0 million, compared to \$6.7 million for the quarter ended June 30, 2015. The increases in total costs and operating expenses primarily reflect activities associated with the third Phase 3 trial of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and an increase in sales and marketing expenses as we prepare for the potential launch of DEXTENZA for ocular pain indication subject to FDA approval of our NDA, as well as preclinical development of the Company's anti-VEGF and TKI programs for the treatment of wet age-related macular degeneration and other back of the eye diseases.
- Ocular Therapeutix generated \$441,000 in revenue during the three months ended June 30, 2016 from product sales of ReSure® Sealant.
- As of June 30, 2016, there were approximately 24.8 million shares issued and outstanding.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am Eastern Time to discuss the Company's financial results and provide a general business update.

The live webcast can be accessed by visiting the investor section of the Company's website at investors.ocutx.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 844-464-3934 (U.S.) or 765-507-2620 (International) to listen to the conference call. The conference ID number for the live call will be 58560807. An archive of the webcast will be available until August 23, 2016 on the company's website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. (NASDAQ: OCUL) is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix's lead product candidate, DEXTENZA™ (dexamethasone insert), is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for dry eye disease. A third Phase 3 clinical trial is being conducted for post-surgical ocular inflammation and pain. For glaucoma and ocular hypertension, the Company plans to initiate the first of two OTX-TP (sustained release travoprost) Phase 3 clinical trials in the third quarter of 2016. Ocular Therapeutix is also evaluating sustained-release injectable drug depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the development and regulatory status of the Company's product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel depot technology and the advancement of the Company's other product candidates, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the sufficiency of the Company's cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation

Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the timing and costs involved in commercializing ReSure® Sealant or any product candidate that receives regulatory approval, the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the sufficiency of cash resources and need for additional financing or other actions and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

Contact:**Investors**

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OCULAR THERAPEUTIX, INC.
STATEMENTS OF OPERATIONS and COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Product revenue	\$ 441	\$ 334	\$ 857	\$ 572
Collaboration revenue	—	125	42	313
Total revenue:	<u>441</u>	<u>459</u>	<u>899</u>	<u>885</u>
Costs and operating expenses:				
Cost of product revenue	105	80	204	136
Research and development	6,978	6,743	14,051	11,462
Selling and marketing	1,492	1,041	2,881	1,911
General and administrative	2,973	2,230	5,379	4,124
Total costs and operating expenses	<u>11,548</u>	<u>10,094</u>	<u>22,515</u>	<u>17,633</u>
Loss from operations	<u>(11,107)</u>	<u>(9,635)</u>	<u>(21,616)</u>	<u>(16,748)</u>
Other income (expense):				
Interest income	80	28	167	68
Interest expense	(418)	(405)	(836)	(910)
Other income (expense), net	—	3	—	3
Total other expense, net	<u>(338)</u>	<u>(374)</u>	<u>(669)</u>	<u>(839)</u>
Net loss	<u>(11,445)</u>	<u>(10,009)</u>	<u>(22,285)</u>	<u>(17,587)</u>
Net loss per share, basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.45)</u>	<u>\$ (0.90)</u>	<u>\$ (0.81)</u>
Weighted average common shares outstanding, basic and diluted	<u>24,770,059</u>	<u>22,167,274</u>	<u>24,761,498</u>	<u>21,765,087</u>
Comprehensive loss:				
Net loss	\$ (11,445)	\$ (10,009)	\$ (22,285)	\$ (17,587)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	10	(8)	78	(8)
Total other comprehensive income (loss)	<u>10</u>	<u>(8)</u>	<u>78</u>	<u>(8)</u>
Total comprehensive loss	<u>\$ (11,435)</u>	<u>\$ (10,017)</u>	<u>\$ (22,207)</u>	<u>\$ (17,595)</u>

OCULAR THERAPEUTIX, INC.

BALANCE SHEETS
(In thousands, except share and per share data)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,170	\$ 30,784
Marketable securities	35,717	74,280
Accounts receivable	223	193
Inventory	149	134
Prepaid expenses and other current assets	715	1,592
Total current assets	84,974	106,983
Property and equipment, net	3,199	3,095
Restricted cash	1,728	228
Total assets	<u>\$ 89,901</u>	<u>\$ 110,306</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,611	\$ 1,957
Accrued expenses and deferred rent	2,342	3,379
Deferred revenue	—	42
Notes payable, net of discount, current	2,466	—
Total current liabilities	6,419	5,378
Deferred rent, long-term	42	68
Notes payable, net of discount, long-term	12,992	15,272
Total liabilities	19,453	20,718
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at June 30, 2016 and December 31, 2015; no shares issued or outstanding at June 30, 2016 and December 31, 2015	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at June 30, 2016 and December 31, 2015, respectively; 24,821,530 and 24,750,281 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	221,897	218,830
Accumulated deficit	(151,461)	(129,176)
Accumulated other comprehensive income (loss)	10	(68)
Total stockholders' equity	70,448	89,588
Total liabilities and stockholders' equity	<u>\$ 89,901</u>	<u>\$ 110,306</u>